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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,188	06/15/2007	Robert D. Hargens	RE/3-33299A	2101

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EXAMINER

VALDEZ, DEVE E

ART UNIT	PAPER NUMBER
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1796

MAIL DATE	DELIVERY MODE
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01/05/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,188	Applicant(s) HARGENS ET AL.	
	Examiner DEVE VALDEZ	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/18/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1175915 (hereinafter '915).

3. Regarding claim 1, '915 teaches a method for the aqueous loading of water soluble and soluble pharmaceutically active substances onto ion exchange resins [0001]. The complex formed between a polymeric material and an active substance can be used in taste masking of bitter drugs, control of the site of administration of drugs, control of the release of flavor substances, and stabilization of unstable substances [0002]. The method for loading active substances into an ion exchange resin is to dissolve an acidic or basic, ionizable active substance in water, and then mix it with a suitable ion exchange resin. Also, '915 teaches a method for preparing a resinate comprising a blending a poorly water soluble or soluble active substance with an ion exchange resin and a solvent selected from the group consisting water, a water miscible solvent, a water-immiscible solvent or mixtures thereof to form an active substance/resin/solvent mixture [0020]. The water immiscible solvents used in the invention are hydrocarbons, halogenated hydrocarbons, ethers, ketones, and esters [0041].

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4. Regarding claim 2, '915 teaches AMBERLITE IRA67 which is a polymeric matrix that has a weak acidic cation exchange resins having carboxylic acid functional groups (Examples 1 and 2).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1175915 (hereinafter '915) in view of WO 01/70194 (hereinafter '194).

9. To further advance the prosecution of this invention, BESS et al. (U.S. Patent No. 7,067,116, hereinafter BESS), which is an English Equivalent of WO 01/70194 will be used in this rejection.

10. Regarding claims 3-6, '915 teaches a method for the aqueous loading of water soluble and soluble pharmaceutically active substances onto ion exchange resins [0001]. However, while '915 teaches the use of hydrocarbons, '915 does not teach a hexane, heptane, octane, isooctane, cyclopentane, cyclohexane, methyl cyclohexane, ethyl cyclohexane, carbon disulfide, trichloroethylene, carbon tetrachloride, benzene, toluene, xylene, propenol, butanol, butanone, and mixtures thereof used for washing the loaded matrix having a polarity of less than 5, 3, and 1.

11. In the same field of endeavor of masking the taste of pharmaceutically active agent, BESS teaches fast dissolving orally consumable films containing an agent to mask the taste of a pharmaceutically active agent which is dextromethorphan hydrobromide and diphenhydramine hydrochloride (Table A) to such as films containing an ion exchange resin as the taste masking agent. The taste-masking agent is an AMBERLITE IRP-69 resin (Col. 4, lines 43-44) and EUDRAGIT S can also be used a taste masked polymer which are coated with solvents such as hexane and toluene (Col. 11, lines 28-30). Even though BESS does not teach hexane as a nonpolar solvent used

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for washing the loaded matrix as a use in his composition, the reference does disclose the use of the claimed hydrocarbon to produce an analogous composition therefore, it would have been obvious to use hexane as the disclosed hydrocarbon of the primary reference.

12. Regarding claims 7-8, '915 teaches anionic exchange resins and cationic exchanges resins such as AMBERLITE IRA67 [0021, Examples 1 and 2]. However, '915 does not teach the polymeric matrix having anionic functional groups used is a hydrogen form cation and the active-loaded hydrogen from cation exchange resin obtained is further neutralized with a metal ion.

13. In the same field of endeavor of taste masking a pharmaceutically active agent, BESS teaches AMBERLITE IRP-69 (Col. 4, lines 60-62) which is a polymeric matrix that has strong acidic cation exchange resin having sulfonic acid functional groups and is neutralized by sodium ions.

14. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to utilize AMBERLITE IRP-69 of BESS for the benefit of taste-masking pharmaceutically active agents such as dextromethorphan hydrobromide.

Response to Arguments

16. Applicant's arguments filed 9/18/2009 have been fully considered but they are not persuasive. The response is insufficient to rebut the anticipatory and prima facie case of obviousness. Despite the applicant's arguments in view of the teachings of the prior art of record, the position is maintained that the prior art renders the invention to be known in the art. Firstly, the applicant's argument regarding the "washing" step of the

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loaded matrix with a non polar substance, the prior art of record EP 1175915 teaches an acrylic anion exchange resin with tertiary amine functionality and a weight capacity between 5.8 and 6.2 meq/g, such as Amberlite IRA67 and addition of 6 grams of water were added to the mixture, the vial was closed and the mixture was shaken (Example 1; [0054]). The position is taken that the shaking step of EP1175915 is equivalent to the "washing step" of the instant invention. Furthermore, EP 1175915 teaches other solvents besides water to be used in the mixture such as immiscible solvents such as hydrocarbons [0041]. Hydrocarbons are well known in the art to be nonpolar.

Therefore, the claims are still anticipated by EP 1175915 because the claims do not exclude the presence of polar solvents such as water and hydrocarbons can be employed into the mixture. Secondly, the secondary reference BESS (WO 01/70194) was relied upon because it taught hydrocarbons such as hexane, heptane, octane, etc. which would act as a nonpolar solvent. It is prima facie case obvious to combine individually old ingredients for their known additive function, i.e., it is obvious to add a known ingredient for its known function; *In re Linder* 173 USPQ 356; *In re Dial et al* 140 USPQ 244.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEVE VALDEZ whose telephone number is (571)270-7738. The examiner can normally be reached on Mon-Thurs, 7:30pm-5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DEVE VALDEZ/

/Rabon Sergent/
Primary Examiner, Art Unit 1796

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